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In the Supreme Court of the United States

OCTOBER TERM, 1974

No. 74-574

NATIONAL NUTRITIONAL FOODS ASSOCIATION, ET AL., PETITIONERS

v.

FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

OPINION BELOW

The opinion of the court of appeals (Pet. App. A1-A88) is reported at 504 F. 2d 761.

JURISDICTION

The judgment of the court of appeals was entered on August 15, 1974. The petition for a writ of certiorari was filed on November 13, 1974. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether the Food and Drug Administration (FDA) may, under Section 401 of the Federal Food, Drug, and Cosmetic Act, promulgate a regulation establishing a definition and standard of identity for dietary supplements of vitamins and minerals that includes minimum and maximum potency requirements for such products, and that also limits the permissible combinations of vitamins and minerals which may be included in such products.

2. Whether under Section 401 of the Act, the FDA has authority to promulgate a definition and standard of identity for dietary supplements which regulate the food products' vitamin and mineral potency.

3. Whether the FDA may promulgate regulations that deem a food to be misbranded under Sections 201(n), 403(a) and 403(j) of the Act if its labeling contains any of six statements which FDA has found, on the basis of substantial evidence adduced at a formal administrative hearing, to be false or misleading.

4. Whether the court of appeals erred in denying petitioners' request to depose the Commissioner of Food and Drugs for the purpose of determining whether he had personally considered the merits of regulations which he signed thirteen days after entering office.

STATUTES AND REGULATIONS INVOLVED

The relevant provisions of Sections 401, 403, and 701 of the Federal Food, Drug and Cosmetic Act of 1938, 52 Stat. 1040, *et seq.*, as amended, 21 U.S.C. 341,

343, and 371, are set forth in Pet. App. C. The relevant regulations, 21 C.F.R. 125.1–125.3, 21 C.F.R. 80.1, 38 Fed. Reg. 20717–20718, 20737–20740, are set forth in Pet. App. D.

STATEMENT

Petitioners challenge the judgment of the court of appeals granting in part and denying in part 15 petitions for review under Section 701(f) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 371(f), of two final regulations of the Food and Drug Administration (FDA).[1]

The FDA's regulations relate to vitamin and mineral supplements that are sold as food ("dietary supplements"). Concerned that the proliferation of such products was causing consumer confusion (Pet. App. A22–A23), the FDA, under the authority of Sections 403(j) and 701(e) of the Act, 21 U.S.C. 343(j), and 371(e), in 1962 proposed a set of regulations "to prescribe * * * label information 'necessary in order fully to inform purchasers' of the value of such products for special dietary uses." 27 Fed. Reg. 5815. In response to comments received, the agency extensively revised the regulations and issued a twenty-two month stay in order to conduct an evidentiary hearing under Section 701(e)(3), 21 U.S.C. 371(e)(3) (Pet. App. A5). Tentative versions of the regulations were published in January 1973 (38 Fed. Reg. 2143) (Pet. App. A6), and final regulations were published in

[1] Petitioners alone have sought a writ of certiorari; none of the other parties who filed petitions for review of the FDA's regulations has sought further review (Pet. App. A4).

August 1973 (38 Fed. Reg. 20717–20718, 20737–20740).[2]

These regulations set forth certain composition and labeling requirements for dietary supplements of vitamins and minerals. Part 125, which prescribes labeling requirements, defines "United States Recommended Daily Allowance" (U.S. RDA)[3] in terms of specified potencies of nineteen vitamins and minerals for each of four categories of consumers.[4] Under the new regulations, labels on foods represented to have special dietary uses because of their vitamin or mineral properties must state the percentage of the U.S. RDA for each of the specified vitamins and minerals provided by the food when consumed in specified quantities during one day (Section 125.3(a), Pet. App. D3). The labels must also contain a statement of the usefulness of the food, which must be limited to a listing of the dietary properties upon which the usefulness is based (Section 125.2(a), Pet. App. D2). If labeling on the food states or implies any of six conclusions suggesting special benefits to health—conclu-

[2] Three of the regulations, 21 C.F.R. 125.1–125.3 ("Part 125") (38 Fed. Reg. 20717–20718), would replace existing regulations issued originally in 1941. The remaining regulations, 21 C.F.R. 80.1 ("Part 80") (38 Fed. Reg. 20737–20740), establish for the first time a definition and standard of identity for dietary supplements.

[3] U.S. RDAs were derived from the Recommended Dietary Allowances published by the Food and Nutrition Board, National Academy of Sciences-National Research Council. (Section 125.1(b)(1), Pet. App. D1.)

[4] Pet. App. D1, Section 125.1. Consumers are classified as infants, children under four years of age, adults and children four years old or older, and pregnant or lactating women.

sions the FDA found to be factually erroneous[5]—the food is misbranded as a matter of law under Sections 403(a) and (j), 21 U.S.C. 343(a) and (j). See also Section 201(n), 21 U.S.C. 321(n).

Part 80 of the regulations establishes definitions and standards of identity for dietary supplements of vitamins and minerals (Pet. App. D4). Only those vitamins and minerals enumerated in Section 80.1(f) may be contained in dietary supplements and their potencies must fall within specified lower and upper limits for each of three categories of consumers (Pet. App. D5). Part 80 also prescribes the format by which included nutrients must be listed on the labels of the foods (Section 80.1(i), Pet. App. D6).

On petitions for review by various members of the industry, the court of appeals, in a lengthy opinion by Judge Friendly, broadly sustained the regulations but held certain provisions invalid, directed that certain others be modified, stayed enforcement of the regulations and remanded the cause to the FDA for further proceedings (Pet. App. A88). Since we rely on so much of the opinion that is challenged by petitioners, we will discuss those portions of the opinion

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[5] Under Section 125.2, the six conclusions are: that the food can effectively treat a disease or symptom in the consumer; that a balanced diet of ordinary foods cannot supply adequate amounts of nutrients; that the soil in which a food is grown may be responsible for a deficiency in a daily diet; that storage, transportation, processing, or cooking of a food may be responsible for a deficiency in a daily diet; that the food has dietary properties where those properties are of no significant value in human nutrition; that a natural vitamin in a food is superior to a synthetic vitamin (Section 125.2(b), Pet. App. D2–D3).

in the context of petitioners' arguments. The court's various other holdings are summarized in the margin.[6]

ARGUMENT

Petitioners' contentions were thoroughly reviewed and correctly rejected by the court of appeals. There is no reason for further review by this Court.

1. Petitioners raise four issues, the first of which is whether the decision below properly upheld "the

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[6] The court rejected the argument that the standards of identity were arbitrary in their entirety, but held that Section 80.1(b)(4) of the regulations should be modified to permit upward revisions in the maximum potencies for particular vitamins or minerals. The court also directed the agency to receive and consider applications to revise dosages upward and to allow combinations. Accordingly, the court stayed the regulations in their entirety to allow the FDA to make such modifications (Pet. App. A34–A40). The court's stay was for six months after judgment or until June 30, 1975, whichever is later (*id.* at A40).

The court held unreasonable the FDA's ban on adding to general purpose foods or dietary supplements certain vitamins and minerals for which no U.S. RDA's have been set (*id.* at A42–A43).

The court held invalid Section 125.1(h), which provides, with certain exceptions, that preparations containing vitamins that exceed the upper limits of their U.S. RDA per serving are drugs (*id.* at A46–A48).

The court sustained the FDA's use of U.S. RDA's to set upper limits of nutrients in dietary supplements (*id.* at A55).

The court ordered the record reopened on remand to allow cross-examination of a witness (Dr. Sebrell), who had been chairman of the body that prepared the 1968 RDA's (*id.* at A55–A68).

Although broadly sustaining Section 125.2(b) of the regulations, which deals with conclusions that cannot be stated or implied on labeling, the court ordered that Section 125.2(b)(2) be qualified with respect to iron (*id.* at A75, A82).

The court exempted fresh fruits and vegetables from Parts 80 and 125 of the regulations (*id.* at A82–A85).

use of a standard of identity under § 401 of the [Act] to prohibit the industry-wide sale of numerous properly-labeled safe food products" (Pet. 2). With respect to this issue, petitioners argue that the legislative history of Section 401 (21 U.S.C. 341) indicates that the FDA had no authority to promulgate a standard of identity that would have the effect of a total ban on the marketing of some "wholesome foods" (*id.* at 4–5) and that any contrary implications from the decision in *Federal Security Administrator* v. *Quaker Oats Co.*, 318 U.S. 218, were laid to rest in *62 Cases of Jam* v. *United States*, 340 U.S. 593.[7]

Section 401 provides, in part, that whenever "in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity * * *." As the court below found, the FDA "had ample evidence to conclude that a consumer seeking a dietary supplement of a given vitamin or mineral, whether singly or in combination with others, is faced with a dazzling array of recommended daily dosages and that a consumer seeking a multiple supplement is faced with an equally dazzling array of combinations; that neither consumer is

[7] The FDA's regulations would treat as misbranded under Section 403(g) of the Act, 21 U.S.C. 343(g), those dietary supplements (1) that contain vitamins and minerals in all non-standardized combinations or (2) whose daily dosage of any nutrient as specified in their labels exceeds the upper limit imposed by the standard (Pet. App. A17–A42).

given any basis for intelligent selection; and that it would 'promote honesty and fair dealing in the interests of consumers,' * * * quoting § 401, to promulgate the qualitative and quantitative standards of identity of new Part 80 * * * " (Pet. App. A22–A24).[8]

There is nothing in the language of Section 401 to indicate that Part 80 of the FDA's regulations is invalid. The term "dietary supplement" has been used in regard to a vast variety of vitamin and/or mineral preparations and there is substantial evidence to support the FDA's conclusion that a standard of identity was needed to standardize "to a single formula (or here a selected group of formulae) what used to be a varied class of products" (Pet. App. A30).[8]

As to the legislative history of Section 401, the passage from the Senate Report quoted by petitioners[9] means only that Section 401 prevented *cheapened* products from being sold under the standard name, but did not ban the sale of cheapened products if they are properly identified as such (*id.* at A30–A33). But here the problem is the confusion generated by the variety of products available, not the confusion caused by selling cheapened products by their standard name

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[8] The court concluded that the FDA "was justified, as a matter of good sense, in concluding that the stated purposes of § 401 would be furthered by promulgating * * * standards of identity in this area so as to allow for some 30-odd products * * * rather than the hundreds now on the shelves of food and drug stores" (Pet. App. A24).

[9] Pet. 5.

(*id.* at A33). The legislative history cited by petitioners is not on point.

That the FDA was empowered, under Section 401, to deal with the problem it had before it in this case is, moreover, clear from the Court's decision in *Quaker Oats, supra,* 318 U.S. at 230–233, which held not only that Section 401 reflected Congress' recognition that consumers might be unable to determine from labels the "relative merits of a variety of products superficially resembling each other," but also that the statute permits the promulgation of "a regulation excluding a wholesome and beneficial ingredient from the definition and standard of identity of a food." The decision in *62 Cases of Jam, supra,* did not disagree with this; instead, the Court held only that a cheapened product—imitation jam—could not be kept off the market so long as it was identified on its label as imitation jam. The case turned on Section 403(c) (21 U.S.C. 343), a provision dealing with misbranded products, not on Section 401, and the Court recognized that under its prior decision in *Quaker Oats,* a properly labeled wholesome product nevertheless "could not be sold" under the regulations, 340 U.S. at 598—which is what petitioners complain about here.[10]

2. Petitioners also argue, as they did below, that the standard of identity authorized by Section 401 cannot be used to regulate a food product's "quantity

[10] The court below left open the possibility that, in light of *62 Cases of Jam*, a manufacturer might be permitted to market as an "imitation" a product containing less than the minimum or more than the maximum limits for vitamins and/or minerals (Pet. App. A28).

per unit," which presumably refers to the vitamin and mineral potency of the product (Pet. 8). But in regard to dietary supplements, "any attempt to prescribe an effective standard of identity had to deal in quantitative as well as qualitative terms" (Pet. App. A51). The usefulness of a dietary supplement depends upon its containing a minimum quantity of vitamins and minerals; after acertain upper threshold, however, further additions of vitamins and minerals have no demonstrated additional effectiveness and are both wasteful and confusing to consumers.[11] The upper limits of U.S. RDAs imposed by Section 80.1(c) and (f)(1), when considered in conjunction with the lower limits imposed, define the standards of identity that are used to classify dietary supplements (Section 80.1(c)(1) and (f)(1), Pet. App. D4).

By setting standards of identity in terms of permissible maxima and minima, the FDA has therefore acted in accordance with the purpose of Section 401 to "promote honesty and fair dealing in the interest of consumers." The limits defining standards of identity set by the FDA's regulations facilitate informed purchasing by consumers, and prevent the marketing of wasteful and confusing potencies greatly in excess of the requirements of human nutrition and health.

3. Under Section 125.2(b) of the regulations (Pet. App. D2–D3), labeling that states or implies any

[11] Petitioners state that "vitamin C has the same 'identity' whether it is sold in quantities of 50, 100 or 500 milligrams" (Pet. 8–9), but the issue is not the identity *per se* of each vitamin and minerals. Moreover, specifically in regard to vitamin C, the court ordered the FDA to consider applications to revise the maximum limit upward (Pet. App. A41).

of six specified conclusions suggesting special benefits to health from dietary supplements falls within Section 403(a) of the Act,[12] which deems misbranded any food product whose label is "false or misleading in any particular." Petitioners argue that the FDA had no power to promulgate this regulation and that it must instead proceed on a case-by-case basis to determine whether a food product is misbranded (Pet. 9–11).

The FDA found that all six of the conclusions suggesting special benefits to health were factually erroneous[13] and, as the evidence in the record showed, Section 125.2(b) was mainly aimed at "scare advertising" that, for example, sought to convince consumers that "a balanced diet of ordinary foods cannot supply adequate amounts of nutrients," Section 125.2(b)(2) (Pet. App. A73, A75, A78).[14] After thoroughly

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[12] 21 U.S.C. 343(a).

[13] See Pet. App. A68–A82. The six conclusions are set forth in n. 5, *supra*.

[14] Using the example of rutin, petitioners state that it was senseless for the FDA in Section 125.2(b)(5) of the regulations to refuse to allow the manufacturer to imply that the product has no nutritional or dietary value (Pet. 10–11). In the court below, Judge Friendly thought there had been no direct challenge to this portion of Section 125.2(b)(5) but, in any event, he upheld the regulation on the following basis (Pet. App. A80):

"[T]he FDA's experience had shown that disclaimers of value did not solve the problem of the misleading effect of including such ingredients in combinations. Thus the FDA could well conclude that in the sale of products consisting solely of such nonessential ingredients a disclaimer could have the effect of calling attention to the potential nutritional value of the product, and it could therefore proscribe such disclaimers as misleading."

reviewing the record, the court below found that the agency's proceedings disclosed "an impressive case * * * of the exaggerated claims made on behalf of various vitamin and mineral products" (Pet. App. A71).

In these circumstances, a requirement that the FDA move against misleading labeling only on a case-by-case basis would stultify enforcement efforts. As this Court recently observed in *Weinberger* v. *Hynson, Westcott & Dunning,* 412 U.S. 609, 626, "this is an age of ever-expanding dockets at the administrative as well as at the judicial level. If the administrative controls over drugs are to be efficient, they must be exercised with dispatch. Only paralysis would result if case-by-case battles in the courts were the only way to protect the public against unsafe or ineffective drugs." [15] The same considerations apply to food products such as those involved here.[16]

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[15] Far from hindering the industry in its labeling preparation, Section 125.2(b) will aid it by giving fair notice of misleading representations that might otherwise expose a company to penalties for misbranding under Section 403, 21 U.S.C. 343.

[16] Petitioners also claim that the court of appeals lacked jurisdiction to entertain the petitions for review with regard to Section 125.2(b) of the regulations, and that only a district court could consider the validity of this part of the regulations (Pet. 9–10). Petitioners assert that the jurisdiction of a court of appeals under Section 701(f) of the Act, 21 U.S.C. 371(f), to review orders of the FDA is limited to orders promulgated under Sections 401 and 403(j), 21 U.S.C. 341 and 343(j), while regulations issued under other sections—Sections 403(a) and 701(a), 21 U.S.C. 343(a) and 371(a)—must be challenged in a district court. In their view, the FDA's authority to issue Section 125.2(b), prohibiting six statements claiming special benefits to health, arises from provisions other than 401 and

4. Citing *Morgan* v. *United States*, 298 U.S. 468, petitioners contend that the court of appeals erred in denying their request to depose the Commissioner of Food and Drugs for the purpose of determining whether he had personally considered the merits of these regulations, which he signed thirteen days after entering office (Pet. 11–14).

Petitioners' request was thoroughly considered and rejected by the court of appeals in an opinion (491 F. 2d 1141 (C.A. 2)) on which we rely (Pet App. B1–B10).[17] The court of appeals noted that "most or all" of the decision in *Morgan* v. *United States*, 298 U.S. 468, was subsequently retracted in *United States* v. *Morgan*, 313 U.S. 409, and that *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U.S. 402, 420, had reaffirmed the last *Morgan* decision by holding that when findings accompany the decision of an admin-

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403(j). The FDA, however, expressly invoked Section 403(j) as authority for issuing Section 125.2(b).

The court of appeals thus correctly concluded (Pet. App. A14–A15 that "[p]etitioners' argument in the main confuses the question of jurisdiction with the merits. If the Commissioner rested his action on an arguable interpretation of §§ 401 or 403(j), our jurisdiction is not defeated by the possibility, even the probability, that we may ultimately reject his interpretation." The petitions for review were therefore properly in the court of appeals. *Bell* v. *Hood*, 327 U.S. 678, 682.

[17] On October 15, 1974, this Court denied petitioners' earlier petition for a writ of certiorari to review the decision of the court of appeals (No. 73–1700). The complex procedural history which resulted in the court of appeals' denial of petitioners' request to depose the Commissioner of Food and Drugs is set forth in our memorandum in opposition to the petition in No. 73–1700. We contended in our memorandum that the only issue ripe for review related to the subject matter jurisdiction of the district court.

istrative agency "there must be a strong showing of bad faith or improper behavior" before testimony concerning the reasons can be required (Pet. App. B7–B8).

Although petitioners argue that the original *Morgan* decision remains unimpaired, they concede that a showing of bad faith or improper behavior is required as a precondition to requiring the testimony of the Commissioner of Food and Drugs (Pet. 13). Here petitioners did not make the requisite showing, as the portion of the opinion of the court of appeals quoted in the margin plainly indicates.[18]

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[18] "The facts of this case do not constitute nearly the showing of bad faith necessary to justify further inquiry; indeed they vividly illustrate the necessity of adhering to the presumption of regularity with respect to the participation of the officer authorized to sign administrative orders, especially in the context of the promulgation of legislative rules as distinguished from adjudication. As stated, the regulations here at issue are the end-product of more than a decade of work by the FDA. Petitioners do not contest that predecessors of Commissioner Schmidt, notably Commissioner Edwards, took an active part in the development of the regulations. All would have been well, apparently, if Commissioner Edwards had continued to serve. But because he resigned in April 1973 and Commissioner Schmidt did not take office until mid-July, promulgation must wait until the new Commissioner could personally familiarize himself with 1,000 pages of formal exceptions, 20,000 letters, and the staff's views about them, and read the relevant portions of the record (or summaries of them). And the same must be true of all the other regulations awaiting the new Commissioner's signature. With the enormous increase in delegation of lawmaking power which Congress has been obliged to make to agencies, both independent and in the executive branch, and in the complexity of life, government would become impossible if courts were to insist on anything of the sort. It would suffice under the circumstances that Commissioner Schmidt considered

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

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FEBRUARY 1975.

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the summaries of the objections and of the answers contained in the elaborate preambles and conferred with his staff about them. There is no reason why he could not have done this even in the limited time available, *cf.* Twin City Milk Producers Ass'n v. McNutt, 122 F. 2d 564, 568–569 (8 Cir. 1941); Florida Economic Advisory Council v. F.P.C., 102 U.S. App. D.C. 152, 251 F. 2d 643, 648 (1957) (Burger, J.), cert. denied, 356 U.S. 959, 78 S. Ct. 996, 2 L. Ed. 2d 1066 (1958), although we do not envy him the task [footnote omitted]. In any event, absent the most powerful preliminary showing to the contrary, effective government requires us to presume that he did. It was his special insight into the workings of the administrative process, as it was and might become, that enabled Mr. Justice Frankfurter in *Morgan IV* to persuade the Court to retreat from *Morgan I* [footnote omitted]. This is no time for an attempt to regain territory so wisely yielded." (491 F. 2d at 1145–1146; Pet. App. B9–B10.)

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